REMARKS

General Matters

According to the Examiner, no new Sequence Listing was received with Applicant's amendment dated April 8, 2003. Hence, enclosed is an additional paper copy of the new Sequence Listing and computer readable version of the same. Please replace the prior Sequence Listing with the Sequence Listing submitted herewith. The Applicants thank the Examiner for pointing out the fact that the new Sequence Listing was not associated with the file and not entered.

The Office Action indicated that claims 1-25 were previously canceled, claims 26-32, 44, 45, 47, and 48 amended, and claims 49-56 added, leaving claims 26-56 under consideration. Applicants note that claims 33-44 and 46 were canceled in Applicant's amendment dated April 8, 2003 and, therefore, only claims 26-32, 45, and 47-56 are currently under consideration.

Written Description Rejection under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 26-29, 31-35, and 37-48 and 49-56 as allegedly failing to meet the written description requirement of 35 U.S.C. § 112, first paragraph. According to the Office, the specification does not provide adequate written description of "a SLIC-1 protein," "at least 90% identical to SEQ ID NO:2," "comprises," "a sequence," "at least . . . contiguous amino acids of . . . a sequence or a SEQ ID NO.," and "at least one immunoreceptor tyrosine motif." Applicants respectfully traverse this rejection. The Office has objected to a number of aspects of the claimed invention and Applicants will address each in turn.

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The specification must describe the claimed invention in such a way that one of ordinary skill in the art would reasonably conclude that the inventors were in possession of the claimed invention. For gene or protein inventions, the Federal Circuit has held that the written description must include more than just a mere description of the function or results. "In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function." *The Regents of the University of California v. Elli Lilly,* 119 F.3d 1559, 1569, 43 U.S.P.Q.2d 1398, 1406 (emphasis added). This additional information may be provided by providing either DNA or amino acid sequences or other physical or structural characteristics of the claimed nucleic acid or protein. It may also be provided if a representative number of species is provided for a claimed genus. *Id.* at 1569. Furthermore, the written description requirement is satisfied if "one of ordinary skill in the art [can] visualize or recognize the identity of the subject matter purportedly described." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968, 63 U.S.P.Q.2d 1609, 1616 (Fed. Cir. 2002).

As indicated above, claims 37-44 and 46 were canceled and are not under consideration. Accordingly, the following comments are directed to claims 26-32, 45, and 47-56.

(a) SLIC-1 in the absence of a SEQ ID NO.

According to the Office Action, "the claims still recite 'SLIC-1' in the absence of a SEQ ID NO. as well as recited limitations that do not encompass critical domain or motifs." (Office Action at 2.) Applicants respectfully note that the presently pending

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claims all refer to SEQ ID NO:2 and modifications of SEQ ID NO:2. Thus, the claims are all presented in the context of this sequence listing. Furthermore, all modifications from SEQ ID NO:2 are defined, as discussed further below.

Additionally, claims 30[1] and 55 require that the claimed SLIC-1 protein "comprise the amino acid sequence of SEQ ID NO:2." Similarly, claim 45 and 50 require the protein to "comprise residues 1-226 of SEQ ID NO:2." The instant specification teaches that these two species (i.e., full-length SLIC-1 and the 1-226 fragment) are capable of binding to PSGL-1. (See Figure 3.) These claims recite a specific sequence for the SLIC-1 protein or fragment. For this additional reason, claims 30, 55, 45, and 50 are properly supported by the instant specification and are in condition for allowance.

(b) Comprises

According to the Office Action there is allegedly insufficient written description of the additional sequences optionally associated with the claimed SLIC-1 proteins or polypeptides that do not contain the entire protein and the term "comprises" is not properly described. (Office Action at 3.) Applicants note that the specification does describe, *inter alia*, T7, GST, maltose E-binding protein, and protein A as examples of entities that may be fused to SLIC-1. All of these entities are conventionally used in the art to prepare fusion proteins. The specification also discloses the actual reduction to practice of several T7-fused forms of SLIC-1 in Example 4 and demonstrates that both the full-length SLIC-1 protein fused to T7 and the 1-226 truncated form of the SLIC-1 protein fused to T7 bind to PSGL-1. (See Figure 3.) Thus, the specification provides a

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[1] Although claim 30 was not rejected for any reason in the June 6, 2003 Office Action, the Office Action indicates that "No claim is allowed." (Office Action at 11.)

number of species that fall within the genus of fusion proteins, providing written description support for this aspect of the claimed invention.

Thus, the specification provides sufficient support for SLIC-1 proteins associated with other polypeptides and are capable of binding to PSGL-1. Thus, the term "comprises" is properly described and supported by the instant specification.

(c) Contiguous sequences

Written description of SLIC-1 protein that "comprises at least . . . contiguous amino acids of SEQ ID NO:2" is found in the specification on page 5, lines 13-15, which states:

> [T]he invention features ***fragments*** of the protein having the amino acid sequence of SEQ ID NO:2, wherein the fragment ***comprises at least*** 15 ***amino acids*** (e.g., 15 ***contiguous*** amino acids) of the amino acid sequence of SEQ ID NO:2.

(Emphasis added.)

Applicants note that SEQ ID NO:2 represents a sequence of 316 contiguous amino acids. Furthermore, at least one specific example of a fragment with at least 15 contiguous amino acids has been described in the specification: 1-226 of SEQ ID NO:2. The claimed sequences all share the common structural feature that they contain at least 15 contiguous amino acids from SEQ ID NO:2 and the genus has further been illustrated by the presentation of two species, namely, the full-length SLIC-1 protein and the 1-226 truncated protein.

The Office Action also indicates that the claims that recite fragments "do not recite functional language." (Office Action at 4.) Following the April 8, 2003, amendment all of the pending claims require that the claimed SLIC-1 protein comprise a

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PSGL-binding fragment. Thus, the pending claims do recite functional language, limiting the claims to proteins that are capable of binding to PSGL-1. Thus, all of the pending claims, which recite both structural and functional limitations, necessarily encompass the critical domains and motifs and all of the pending claims are properly described by the instant specification.

Therefore, a skilled artisan would recognize that Applicants were in possession of the genus of all contiguous sequences that can be derived from SEQ ID NO:2 because the identity of any species of this genus can be immediately envisaged. Moreover, the claimed contiguous sequences are limited to those contiguous sequences that are capable of binding to PSGL-1. Thus, the claimed "contiguous sequences" are properly described by structure and function.

(d) At least 90% identical to SEQ ID NO:2

According to the Office Action, the specification does not provide adequate written support for the "at least 90% identical to SEQ ID NO:2" limitation.

Written description of "a polypeptide which is at least 90% identical to SEQ ID NO:2" and retains the functional activity of SEQ ID NO:2 is found in the specification on page 24, lines 33-38, which states:

> In other embodiments, the SLIC-1 protein is **substantially identical to SEQ ID NO:2, and retains the functional activity** of the protein of SEQ ID NO:2, yet differs in amino acid sequence due to natural allelic variation or mutagenesis, as described in detail in subsection I above. Accordingly, in another embodiment, **the SLIC-1 protein is a protein which comprises an amino acid sequence at least about 50%, 55%, 60%, 65%,70%, 75%, 80%, 85%, 90%, 95%, 96%, 97%, 98%, 99% or more identical to SEQ ID NO:2**.

(Emphasis added.)

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Methods for identifying percent identity are well known in the art and are described on page 25 of the specification. Furthermore, assays for determining protein binding are very well known in the art. Thus, the skilled artisan can readily determine which SLIC-1 proteins are at least 90% identical to SEQ ID NO:2 and are capable of binding to PSGL-1. These sequences all contain the common structural feature that they are at least 90% identical to SEQ ID NO:2.

A skilled artisan would, therefore, conclude that Applicants were in possession of the genus of polypeptides that are at least 90% identical to SEQ ID NO:2 and are capable of binding to PSGL-1 and the phrase "at least 90% identical to SEQ ID NO:2" is properly described by the instant specification.

(e) Elements of claim 40 and claim 46

According to the Office Action, there is not sufficient written description for the elements of claim 40 and claim 46. Because claims 40 and 46 were canceled without prejudice in the April 28, 2003, amendment, this rejection is moot.

In view of the foregoing, Applicants submit that pending claims 26-32, 45, and 47-56 are properly supported by the instant specification and request that the written description rejection be reconsidered and withdrawn.

Enablement Rejection under 35 U.S.C. § 112, first paragraph

According to the Office Action claims 26-29, 31-35, 37-48 and claims 49-56 are not enabled for "any 'SLIC-1 protein or polypeptide' including 'at least 90% identical to SEQ ID NO:2' 'comprises' 'a sequences' or 'at least . . . contiguous amino acids . . . of a

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sequence or a SEQ ID NO,' encompassed by the claimed invention." (Office Action at 5.)

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosure coupled with information known in the art without undue experimentation. *United Stated v. Telectronics, Inc.,* 857 F.2d 778, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988). The test for enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 190 U.S.P.Q. 214 (C.C.P.A. 1976) (emphasis added).

Methods of identifying sequence identity are very well known in the art and described in the instant specification, for example, on page 25 of the original specification. Method for determining protein binding are likewise very well known in the art. One method for determining protein binding is an assay that involves co-immunoprecipitation followed by western blot analysis as reported in Example 4 and depicted in Figure 3. The specification also provides guidance on which regions of SEQ ID NO:2 are most important to binding activity. Finally, merely because certain species may be inoperable does not automatically render the claimed invention nonenabled. *In re Smythe,* 480 F.2d 1376, 178 U.S.P.Q. 279 (C.C.P.A. 1973).

It would, therefore, require nothing more than ordinary experimentation to determine which proteins comprising SLIC-1 proteins, SLIC-1 protein variants, or SLIC-1 fragments bind PSGL-1. Moreover, the "90% identity" and "contiguous amino acids" limitations provide the skilled artisan with further guidance in the selection of SLIC-1 proteins that bind to PSGL-1. Thus, the instant specification places the skilled artisan into possession of the claimed methods and enables them to make and use the claimed

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SLIC-1 proteins and fragments that have at least 90% identity or comprise contiguous amino acids from the SLIC-1 protein described in SEQ ID NO:2.

Additionally, according to the Office Action, the specification is enabling for "SLIC-1 set forth in SEQ ID NOS: 1 and 2." (Office Action at 5) Thus, claim 30[2] and claim 55, which claim proteins comprising the amino acid of SEQ ID NO:2, are properly enabled by the instant specification. Claims 45 and 50, which relate to the 1-226 truncated SLIC-1 protein describe in Example 4 and shown to bind to PSGL-1 (see Figure 3), are likewise enabled by the instant specification.

According to the Office Action, the specification "while being enabling for 'inhibiting signal transduction, associate with the cytoskeleton or cell adhesion via PSGL-1' does not reasonably provide enablement for any 'activity of said SLIC-1 protein', encompassed by the claimed invention." (Office Action at 5.) And the Examiner invited the Applicants to "amend the claims to recite specific measurable endpoints." (Office Action at 10.) All of the currently pending claims are limited to methods for identifying compounds that inhibit or increase the binding of SLIC-1 protein to PSGL-1 and, therefore, the only SLIC-1 activity encompassed by the pending claims is the ability to bind to PSGL-1. Applicants submit that the ability of the claimed SLIC-1 proteins and fragments to bind PSGL-1 is a "specific measurable endpoint" that enables one of ordinary skill in the art to make and use the claimed invention.

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[2] Again, claim 30 was not rejected as non-enabled, but the Office Action indicates that "No claim is allowed." (Office Action at 11.)

(f) Elements of claim 40 and claim 46

According to the Office Action, claim 40 and claim 46 are not properly enabled. Because claims 40 and 46 were canceled without prejudice in the April 28, 2003, amendment, this rejection is moot.

Applicant submit that one skilled in the art could make and use the claimed invention from the disclosure coupled with information known in the art without undue experimentation and request that the enablement rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to deposit account 06-0916.

Respectfully submitted,
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Dated: September 9, 2003

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